

FISCAL NOTE PRIVATE COST

- I. Department: Department of Insurance, Financial Institutions and Professional Registration**
Division Title: State Board of Pharmacy
Chapter Title: General Rules

Rule Number and Title:	20 CSR 2220-2.200 (Sterile Pharmaceuticals)
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
97-123	Missouri Sterile Compounding Pharmacies	\$ 99,245 <i>(Y1 Implementation)</i>
97-123	Missouri Sterile Compounding Pharmacies	\$ 2,289,007.48 <i>recurring annually over the life of the rule</i>
125	Non-Resident Sterile Compounding Pharmacies	\$ 572,251.87 <i>recurring annually over the life of the rule</i>

III. ASSUMPTIONS/WORKSHEETS

The following general estimations were used to calculate private fiscal costs:

- The board conducted a survey in 2014 of all Missouri resident and non-resident sterile compounding pharmacies. Private fiscal costs were estimated based on survey results which reflect the most recent board data on the scope of sterile compounding activities performed by Missouri licensed pharmacies. According to survey results, a significant number of pharmacies are currently complying with the majority, if not all, of the proposed rule requirements. Accordingly, fiscal impact will likely be significantly lower than estimated, however, costs have been estimated as reflected herein to ensure full compliance with Chapter 536, RSMo.
- Approximately 123 pharmacies were licensed by the board to perform sterile compounding as of May 1, 2016. Based on survey results and Board licensing data, the Board estimates:
 - Twenty-eight (28) pharmacies are/will be engaged in only Risk Level 1 compounding (approx. 23% of sterile compounding pharmacies)
 - Sixty-eight (68) pharmacies are/will be engaged in Risk Level 2 or lower compounding (55% of sterile compounding pharmacies)
 - Twenty-seven (27) pharmacies are/will be engaged in Risk Level 3 compounding or lower compounding (22% of sterile compounding pharmacies)
- The proposed amendment substantively incorporates current United States Pharmacopeia (USP) Chapter 797 requirements. After consultation with Missouri hospital pharmacy directors, the

Missouri Hospital Advisory Commission and representatives from the Missouri Hospital Association, the Board understands the majority of Class-B hospital pharmacies licensed with the Board are currently required to comply with USP Chapter 797 by the Centers for Medicare and Medicaid Services (CMS) and/or the Joint Commission which governs hospital accreditation.

4. Approximately 24% of Missouri sterile compounding pharmacies are licensed Class-B hospital pharmacies and are estimated to be engaged in Risk Level 2 and 3 compounding. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies impacted by proposed requirements that mirror USP Chapter 797 has been reduced by 20% to:
 - Twenty-eight (28) Risk Level 1 pharmacies
 - Fifty-Four (54) Risk Level 2 pharmacies, and
 - Twenty-two (22) Risk Level 3 pharmacies
5. The 20% reduction represents Class-B hospital pharmacies that are currently required to comply with Chapter 797 and would not incur any additional fiscal costs. The reduction has been adjusted to account for license duplication and other allied entities under common ownership or control of the hospital that may also be licensed as a Class-B hospital pharmacy.
6. An hourly pharmacist salary of \$59.24 and an hourly pharmacy technician salary of \$18.47 was utilized which represents an average of the mean hourly wage for pharmacists/technicians practicing in a General Medical and Surgical Hospital setting (\$57.43) and pharmacists/technicians practicing in an Outpatient Care Center setting (\$61.05) as reflected in the United States Bureau of Labor Statistics Occupational Employment and Wages data for May 2015. An average of the identified hourly rates was selected due to the variant practice settings of Board licensees/registrants.
7. Where applicable, costs were projected using the estimated hourly pharmacy technician salary for activities not required to be performed by a pharmacist.
8. Compounding staff per pharmacy can fluctuate widely depending on the scope and level of compounding services performed. The Board estimates the average pharmacy will be required to perform initial training/assessment for two (2) new sterile compounding technicians per year and further estimates a total of three (3) sterile compounding employees per pharmacy.
9. The Board estimates 261 business days per year based on the United States Office of Personal Management's 28-year work-calendar study.
10. Except as otherwise provided herein, fiscal costs were estimated based on Board licensing data as of May 1, 2016. The number of sterile compounding pharmacies and scope of sterile compounding activities is estimated to remain consistent over the life of the rule.
11. Fiscal costs were also based on estimates from selected sterile compounding pharmacies, current market prices and current vendor/certification fees and have been adjusted to reflect compliance costs required by the current rule.
12. Based on current licensing data and 2014 survey results, the Board estimates non-resident sterile compounding pharmacies will incur 25% of total fiscal costs estimated for Missouri resident pharmacies.
13. The Board anticipates the total estimated costs may vary with inflation and increase at the rate projected by the Legislative Oversight Committee.

Facilities/Equipment Costs:

14. The proposed certification/recertification requirements for ISO classified areas will primarily be applicable to Risk Level 2 and 3 pharmacies and are similar to current USP Chapter 797 requirements. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been adjusted to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
15. Due to the potential longevity of properly functioning primary engineering controls, the Board estimates 25-new primary engineering controls will be purchased annually by sterile compounding pharmacies. Additionally, the Board estimates 25 pharmacies will be required to recertify primary engineering controls (PECs) because of deficiencies, relocation or other PEC changes.
16. The Board estimates seven (7) new Missouri sterile compounding pharmacies will require initial certification of ISO classified areas per year.
17. An estimated 50 pharmacies will be required to place or install a line of demarcation.

Description of Cost	Calculation	Total
Line of Demarcation	• Tape/Marker Costs: \$ 3.00 per tape roll/marketing equipment x 50 pharmacies	\$ 150 (Y1 implementation)
PEC Initial Certification (all risk levels)	• Certification Costs: 25 pharmacies X \$ 200 certification fee	\$5,000 annually
PEC Recertification (all risk levels)	• Certification Costs: 25 pharmacies X \$ 200 certification fee	\$5,000 annually
ISO Classified Areas Certification (New)	• Certification Costs: \$ 2,750 x 7 new pharmacies	\$19,250 annually
ISO Classified Areas Certification (Ongoing)	• Certification Costs: \$ 2,750 x 76 Risk Level 2 & 3 pharmacies x 2 times per year	\$418,000 annually
	TOTAL	\$ 150 (Y1 implementation) \$ 447,250 (annually)

Garbing/Hand Hygiene Costs:

18. The proposed garbing/hand hygiene requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
19. The Board estimates the average pharmacy will employ approximately 3 staff people to perform sterile compounding daily and further estimates two (2) garbing changes per person/per day.
20. The Board estimates a total cost of \$4.80 for Risk Level 1 garbing and \$5.65 for Risk Level 2 and three (3) garbing based on the following estimated costs: beard covers (\$.08), face mask (\$.32), gown (\$ 3.50), gloves (\$.55), hair cover (\$.35), sterile gloves (\$1.20) and shoe covers (\$.20)

Description of Cost	Calculation	Total
Garbing (Risk Level 1: Beard cover, face mask, gloves, gown, hair cover)	<ul style="list-style-type: none"> Garbing (\$ 4.80) x 28 pharmacies x 3 staff people x 2 changes per day x 261 business days. 	\$ 210,470.40 annually
Garbing (Risk Level 2 & 3: Beard cover, face mask, sterile gloves, gown, hair cover, shoe covers)	<ul style="list-style-type: none"> Garbing (\$ 5.65) x 76 pharmacies x 3 staff people x 2 changes per day x 261 business days. 	\$ 672,440.40 annually
	TOTAL	\$ 882,910.80 annually

Environmental Monitoring/Sampling Costs:

21. The proposed amendment delineates specific time intervals for the air monitoring and surface sampling currently required for Risk Level 2 and Risk Level 3 pharmacies.
22. The proposed air monitoring requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
23. An average of two (2) surface samples is estimated per pharmacy during each required sampling using settling plates. Costs to incubate samples have been later reflected in the aseptic technique skill assessment section which includes costs for purchasing an incubator which could also be used for settling plates.
24. The Board estimates 15-minutes of technician time will be separately required to perform/document the required air monitoring and the required surface sampling.

Description of Cost	Calculation	Total
Air Monitoring (every six (6) months)	<ul style="list-style-type: none"> Technician Salary Costs: \$4.62 (¼ of 18.47 hourly wage) x 76 Risk Level 2 & 3 pharmacies x 2 air monitoring collections per year. 	\$ 702.24 annually
Surface Sampling (Risk Level 2)	<ul style="list-style-type: none"> Sample Costs: \$2.00 per settling plate x 2 samples per year x 68 Risk Level 2 pharmacies = \$ 272 annually <li style="text-align: center;">+ Technician Salary Costs: \$4.62 (¼ of 18.47 hourly wage) x 68 Risk Level 2 pharmacies x 2 samples per years = \$ 628.32 annually 	\$ 900.32 annually
Surface Sampling (Risk Level 3)	<ul style="list-style-type: none"> Sample Costs: \$2.00 per settling plate x 2 samples x 12 samples per year x 27 Risk Level 3 pharmacies = \$ 1,296 annually <li style="text-align: center;">+ Technician Salary Costs: \$4.62 (¼ of 18.47 hourly wage) x 12 samples per year x 27 Risk Level 3 pharmacies= \$ 1,496.88 annually 	\$ 2,792.88 annually
	TOTAL	\$ 4,395.44 annually

Aseptic Technique Skill Assessment Costs:

25. Sterile compounding pharmacies are currently required to perform both initial and ongoing process validation which has been renamed media-fill testing in the proposed amendment. Accordingly, media-fill testing costs have been estimated only to the extent the proposed amendment exceeds the current process validation requirements.
26. The Board estimates approximately two (2) new personnel will be hired and require an annual aseptic technique skill assessment per pharmacy. The Board estimates the average aseptic technique skill assessment will require one (1) hour of both pharmacist and technician time.
27. The current rule requires Risk Level 2 and 3 pharmacies to perform a competency assessment via process simulation. Accordingly, initial assessment costs have not been estimated for Risk Level 2 and 3 pharmacies.
28. Absent specific data, the Board estimates approximately one (1) pharmacy technician per year will require an aseptic technique reevaluation assessment under section (10)(C).
29. While media-fill testing can be outsourced, in-house media fill testing through the use of media-fill kits and an incubator is currently the most cost-efficient method for testing. The Board estimates 70% of pharmacies already have equipment for media fill testing and has consequently estimated only 30% of affected pharmacies may opt to purchase an incubator.
30. The proposed aseptic technique skill assessment requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.

Description of Cost	Calculation	Total
Initial aseptic skill assessment evaluation (Risk Level 1)	<ul style="list-style-type: none"> Pharmacist Observation Costs: \$59.24 per hour x 2 employees per year x 28 pharmacies = \$ 3,317.44 + Technician Salary Costs (\$1,034.32): \$18.47 per hour x 2 employees x 28 pharmacies 	\$ 4,351.76 annually
Annual aseptic skill assessment evaluation (all risk levels)	<ul style="list-style-type: none"> Pharmacist Observation Costs (\$ 18,482.88): \$59.24 per hour x 3 employees per year x 104 pharmacies + Technician Salary Costs (\$ 5,762.64): \$ 18.47 per hour x 3 employees x 104 pharmacies 	\$ 24,245.52 annually
Additional 6-month aseptic skill assessment (Risk Level 3)	<ul style="list-style-type: none"> Pharmacist Observation Costs: \$59.24 per hour x 3 employees per year x 22 pharmacies = \$ 3,909.84 + Technician Salary Costs: \$ 18.47 per hour x 3 employees x 22 pharmacies = \$1,219.02 	\$ 5,128.86 annually
Reevaluation of aseptic technique	<ul style="list-style-type: none"> Pharmacist Observation Costs (\$ 6,160.96): \$59.24 per hour x 1 employee per year x 104 pharmacies + Technician Salary Costs (\$ 1,920.88): \$ 18.47 per hour x 1 employee x 104 pharmacies 	\$ 8,081.84 annually

Media-Fill Equipment	<ul style="list-style-type: none"> Incubator: \$345 per incubator x 31 pharmacies (30% of 104 pharmacies w/ reduction in Risk Level 2 and 3 pharmacies) 	\$ 10,695 (Y1 implementation)
Additional 6-Month Media-fill Test (Risk Level 3)	<ul style="list-style-type: none"> Media-Fill Test Kits: \$ 65 per kit x 22 pharmacies x 1 additional test x 3 employees 	\$4,290 annually
Reevaluation of aseptic technique media-fill	<ul style="list-style-type: none"> Media-Fill Test Kits: \$ 65 per kit x 1 employee x 104 pharmacies 	\$ 6,760 annually
	TOTAL	\$ 10,695 (Y1 implementation) \$ 52,857.98 annually

Cleaning and Disinfection Costs:

31. The proposed amendment incorporates current USP Chapter 797 cleaning and disinfection requirements. Accordingly, the number of Risk Level 2 pharmacies has been adjusted as described above. The proposed cleaning/disinfection intervals for Risk Level 3 pharmacies will remain consistent. Accordingly, no additional costs have been calculated.
32. The Board estimates the average pharmacy will hire/train two (2) new sterile compounding technicians per year to perform the required cleaning and further estimates annual cleaning/disinfection training will be required for three (3) sterile compounding employees per pharmacy.
33. The Board estimates the current training/observation requirements will require a total of one (1) hour staff time for both the trainee and the observing training pharmacist.
34. The Board estimates cleaning times will be increased by 1-hour daily and 2-hours monthly for Risk Level 1 pharmacies. For Risk Level 2, the Board estimates cleaning times will be increased by 30-minutes daily and 1-hour monthly.
35. Approximately 88% of sterile compounding pharmacies reported using sterile alcohol for disinfection in the Board's 2013 sterile compounding survey. The total number of sterile compounding pharmacies required to buy sterile alcohol has been correspondingly decreased by 88% to 15 pharmacies. The Board estimate an average of three (3) gallons of sterile alcohol will be required per pharmacy per month.
36. The Board estimates pharmacies will be required to expend an additional \$5 per month in cleaning supplies not already required or used by the pharmacy to meet current rule requirements.

Description of Cost	Calculation	Total
Daily Cleaning (Risk Level 1)	<ul style="list-style-type: none"> Technician Salary Costs: \$ 18.47 per hour x 28 pharmacies x 1-hour x 261 business days. 	\$ 134,978.76 annually
Monthly Cleaning (Risk Level 1)	<ul style="list-style-type: none"> Technician Salary Costs: \$ 18.47 per hour x 2-hours x 28 pharmacies x 261 business days. 	\$ 269,957.52 annually
Daily Cleaning (Risk Level 2)	<ul style="list-style-type: none"> Technician Salary Costs: \$ 9.24 (½ of \$18.47 per hour) x 54 pharmacies x 261 business days. 	\$ 130,228.56 annually
Monthly Cleaning (Risk Level 2)	<ul style="list-style-type: none"> Technician Salary Costs: \$ 18.47 per hour x 54 pharmacies x 1-hour x 261 business days. 	\$ 260,316.18 annually
Initial Cleaning training and direct visual observation (All risk levels)	<ul style="list-style-type: none"> Pharmacist Observation Costs (\$12,321.92): \$59.24 per hour x 2 employees per year x 104 pharmacies + Technician Salary Costs (43,841.76): \$18.47 per hour x 2 employees x 104 pharmacies 	\$ 16,163.68 annually
Annual Cleaning training and direct visual observation (All risk levels)	<ul style="list-style-type: none"> Pharmacist Observation Costs (\$18,482.88): \$59.24 per hour x 3 employees per year x 104 pharmacies + Technician Salary Costs (\$5,762.64): \$18.47 per hour x 3 employees x 104 pharmacies 	\$ 24,245.52 annually
Sterile alcohol	<ul style="list-style-type: none"> Purchase costs: \$ 55 per gallon x 3 gallons per month x 15 pharmacies x 12 months 	\$ 29,700 annually
Other cleaning supplies (germicidal agents, low-lint supplies)	<ul style="list-style-type: none"> \$5 per month x 104 pharmacies 	\$ 520 annually
TOTAL		\$ 866,110.22 annually

Miscellaneous Costs:

37. The rule requires compliance with selected provisions of USP Chapter 797. Accordingly, costs have been estimated for purchasing a current copy of the United States Pharmacopeia and the National Formulary (USP-NF). The Board estimates the total number of pharmacies required to purchase the USP-NF will include 28 Risk Level 1 pharmacies, 54 Risk Level 2 pharmacies and 22 Risk Level 3 pharmacies (104 pharmacies). The number of affected pharmacies has been reduced to reflect Class-B hospital pharmacies that are currently required to comply with USP Chapter 797 and presumably already have access to the current USP-NF.
38. The proposed aseptic technique, cleaning and training requirements are intended to reduce incidences of environmental and microbial contamination and the need for the proposed

remedial investigation. In the absence of more specific data, the Board estimates the average pharmacy will spend two (2) hours of pharmacist staff time to conduct remedial investigations per year.

39. The Board estimates an additional one (1) hour of pharmacist time would be required to comply with the additional documentation and policy and procedure requirements of the rule.
40. The Board estimates an additional thirty (30) minutes of pharmacy technician time would be required to comply with the additional documentation, verification and recording requirements per month.

Description of Cost	Calculation	Total
USP-NF	• Purchase Costs: \$ 850 x 104 pharmacies	\$ 88,400 Y1 implementation
Remedial Investigations	• Pharmacist Costs: \$59.24 per hour x 2-hours per year x 123 pharmacies	\$ 14,573.04 annually
Pharmacist Misc. activities	• Pharmacist Costs: \$59.24 per hour x 1-hour per year x 123 pharmacies	\$ 7,286.52
Technician Misc. Activities	• Technician Salary Costs: \$ 9.24 (½ of \$18.47 per hour) x 123 pharmacies x 12-months.	\$ 13,623.48 annually
	TOTAL	\$ 88,400 (Y1 implementation) \$ 35,483.04 (annually)